Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2007 list were published in the Federal Register in October 2007.

New Approval(s)

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-277

Trade Name:	Comfortis™
Ingredients:	Spinosad
Sponsor:	Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date:	September 25, 2007
Status:	Rx
Route:	Oral
Species:	Dogs
Drug Form:	Chewable tablet
Concentration:	140 mg, 270 mg, 560 mg, 810 mg, 1620 mg tablets
Indications:	Kills fleas and is indicated for the prevention and treatment of flea infestations (*Ctenocephalides felis)* on dogs for one month.
Exclusivity:	Five years
Patent(s):	6,664,237 Expires: August 12, 2019

21 CFR 520.2130

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-233

Trade Name:	Optaflexx®, MGA®, Rumensin®, and Tylan®
Ingredients:	Ractopamine hydrochloride, melengestrol acetate, monensin, tylosin phosphate
Sponsor:	Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date:	September 11, 2007

This supplemental application provides for; an increased level of monensin in four-way combination Type C medicated feeds containing ractopamine, melengestrol, monensin, and tylosin for heifers fed in confinement for slaughter, a revision of bacterial nomenclature, from *Actinomyces (Corynebacterium) pyogenes* to *Arcanobacterium (Actinomyces) pyogenes*, and an increase in liver tolerance, from 0.05 to 0.10 parts per million (ppm) for monensin.

21 CFR 556.420, 558.500 72 FR 56898

NADA Number: 140-901

Trade Name:	Adequan® i.m.
Ingredients:	Polysulfated glycosaminoglycan
Sponsor:	Luitpold Pharmaceuticals, Inc.
Approval Date:	September 10, 2007

This supplemental application provides for the revised food safety warning statement, “Do not use in horses intended for human consumption”.

21 CFR 522.1850 72 FR 56896

NADA Number: 140-958

Trade Name: Equiphen®
Ingredients: Phenylbutazone
Sponsor: Luitpold Pharmaceuticals, Inc.
Approval Date: September 26, 2007

This supplemental application provides for the revised food safety warning statement, "Do not use in horses intended for human consumption".

21 CFR 522.1720(c) 72 FR 60550

Patent Extension

NADA Number: 141-217

Patent number: 4,937,234
Extension Period: 5 years
Expiration Date: August 10, 2013

Change of Sponsor

NADA Numbers: 012-350, 013-149, 013-461, 033-165, 034-393

From: Merial Ltd.
To: Huvepharma, AD
33 James Boucher Blvd.
Sophia 1407
Bulgaria
Drug Labeler Code: 016592

72 FR 60551, October 25, 2007

NADA Numbers: 140-951, 141-090, 141-153, 141-158, 141-190, 141-194, 141-195

From: Schering-Plough Animal Health Corp.
To: Huvepharma, AD
33 James Boucher Blvd.
Sophia 1407
Bulgaria
Drug Labeler Code: 016592

72 FR 60552, October 25, 2007

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2007 list were published in the Federal Register in October 2007.

Labeling Revisions

NADA Number: 141-082

Trade Name:	Doxirobe® Gel.
Ingredients:	Doxycycline hyclate
Sponsor:	Pharmacia & Upjohn Co., A Division of Pfizer, Inc.
Effective Date:	October 15, 2007

This supplemental application provides for the registered trademark ® to be changed to a trademark ™.

Notices

The Food and Drug Administration (FDA) announces the availability of guidance for industry (178) entitled, "Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims." This guidance provides recommendations to industry relating to study design and describes the criteria that the Center for Veterinary Medicine (CVM) intends to use to evaluate effectiveness studies for swine respiratory disease (SRD) claims.

Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Please include one self-addressed adhesive label.

Persons with access to the Internet may obtain the guidance from either the CVM home page (http://www.fda.gov/cvm) or the Division of Dockets Management Web site (http://www.fda.gov/ohrms/dockets/default.htm).

FOR FURTHER INFORMATION CONTACT: Michelle L. Stull, CVM (HFV-133), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-5058, e-mail: michelle.stull@fda.hhs.gov.

72 FR 56079, October 2, 2007

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The FDA solicits comments on the effect of regulatory review period on patent terms restoration, due diligence petitions, filing, format, and content of petitions. Fax written comments to the Office of Management and Budget (OMB) at: 202-395-6974 (Attn: FDA Desk Officer) or e-mail to baguilar@omb.eop.gov by November 13, 2007. All comments should be identified with the OMB control number 0910-0233 and the FDA docket number: 2007N-0240.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857, 301-827-4816.

72 FR 57951, October 11, 2007

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The FDA solicits comments on focus groups as used by the FDA. Fax written comments to the Office of Management and Budget (OMB) at: 202-395-6974 (Attn: FDA Desk Officer) or e-mail to baguilar@omb.eop.gov .by November 14, 2007. All comments should be identified with the OMB control number 0910-0497 and the FDA docket number: 2007N-0098.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857, 301-827-4659.

72 FR 58310 October 15, 2007

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